(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 September 2005 (09.09.2005)

PCT

(10) International Publication Number
WO 2005/082369 A1

(51) International Patent Classification[7]: A61K 31/485, 31/4468, 31/454, 9/72, 9/127, A61M 15/00, A61P 29/00

(21) International Application Number: PCT/CA2004/001578

(22) International Filing Date: 27 August 2004 (27.08.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PCT/CA2004/000303
1 March 2004 (01.03.2004) CA

(71) Applicant *(for all designated States except US)*: **DELEX THERAPEUTICS INC.** [CA/CA]; 6535 Millcreek Drive, Unit 62, Mississauga, Ontario L5N 2M2 (CA).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **HUNG, Orlando Ricardo** [CA/CA]; 933 Greenwood Avenue, Halifax, Nova Scotia B3H 3L1 (CA). **SHAFER, Steven Louis** [US/US]; 531 Sullivan Drive, Mountain View, CA 94041 (US). **PLIURA, Diana Helen** [CA/CA]; 5032 Brandy Lane Court, Mississauga, Ontario L5M 5A2 (CA).

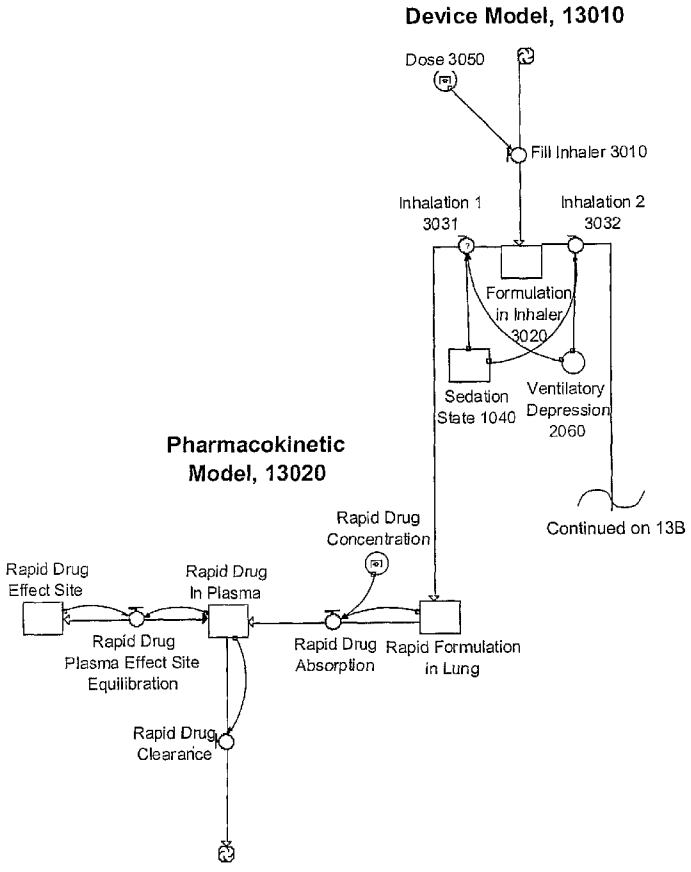
(74) Agents: **TORYS LLP** et al.; Maritime Life Tower, Suite 3000, 79 Wellington St. W., Box 270, TD Centre, Toronto, Ontario M5K 1N2 (CA).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

[Continued on next page]

(54) Title: OPIOID DELIVERY SYSTEM

The elements of the invention, wherein two opioids are administered through inhalation.



(57) Abstract: An opioid formulation for pulmonary administration in the treatment or management of pain, a pulmonary drug delivery device containing, method of administering, kit containing, and uses of same. The formulation contains at least one rapid-onset opioid and preferably also contains a sustained-effect opioid to reduce the frequency of administration. The invention employs the side effects of the opioid formulation to permit patients to self-limit drug intake, thereby avoiding toxicity while achieving analgesia. A pharmacokinetic and pharmacodynamic model is employed to determine optimum drug formulations and optimum parameters for administration.

WO 2005/082369 A1

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.